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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,727

02/25/2004

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65937-0045

2729

10291 7590 06/01/2009
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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

06/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,727	Applicant(s) MARK, JOSEPH L.
	Examiner Jeffrey G. Hoekstra	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 02/16/2009, amended claim(s) 1, 9, 10, 12, 14, 22, 23, and 25 is/are acknowledged. The current rejections of the claim(s) 1-30 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-10, 12, 14-23, 25, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 2002/0082519, hereinafter Miller) in view of Moore (US 2,866,457).
4. For claims 1 and 14 Miller discloses a biopsy system (as best seen in Figure 12) comprising a body member (as best seen in Figure 12) and comprising *inter alia*: a vacuum assisted biopsy device (300) (paragraphs 141-146), a first fluid source (400) (as best seen in Figure 12) in fluid communication with a first input port (as best seen in Figure 12), a second fluid source (paragraph 90; "anesthetic") in fluid communication with a second input port, and a fluid connector (around 402) configured to provide the first fluid source in communication with the biopsy device (as best seen in Figure 12) and including a first valve (402) inherently having a cracking pressure and which is selectively opened by a change in pressure within an outlet port (paragraphs 141-146) (as best seen in Figure 12). In regards to claims 9 and 22, Miller discloses that the

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cracking pressure is less than or equal to a vacuum created in the fluid connector by the biopsy device (paragraph 143). In regards to claims 12 and 25, Miller discloses drawing a predetermined amount of fluid from a fluid source (paragraph 142).

5. For claims 1 and 14, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the first valve is a check valve and the fluid connector includes a second check valve for providing the second fluid source in communication with the biopsy device.

6. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39), comprising *inter alia*: a first valve (9) comprising a check valve (9) in fluid communication with a first inlet port (around 10) and selectively opened by a change of pressure (column 2 lines 22-44) within an outlet port (around 8), wherein the check valve is capable of selectively opening when a vacuum is created in the fluid connector, and the fluid connector includes a second check valve (22) for providing the second fluid source (26) in communication fluid communication with a fluid connector (as best seen in Figure 1).

7. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with

the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

8. In regards to claims 2 and 15, Miller in view of Moore does not expressly disclose a duckbill valve member. However, Moore teaches that any check valve well known in the art can be used. Applicant states in the specification that a duckbill-style valve is well known (paragraph 40). The claimed invention would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Miller and Moore teach using valves for fluid management, it would have been obvious to one skilled in the art at the time of the invention to substitute one valve for the other to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

9. In regards to claims 3, 4, 16, and 17, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the check valves comprise resiliently compressible valve members secured in a valve seat. Moore teaches the check valves comprising resiliently compressible valve members (around and including spring 25 in Figure 1) secured in a valve seat (around 25 in Figure 1). All the claimed elements were known in the prior art and one skilled in the art could have combined the

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elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

10. In regards to claims 5-7 and 18-20, Miller discloses a biopsy system, wherein the first fluid source is an isotonic solution (saline; paragraphs 141-144) and the second fluid source being an anesthetic (paragraph 90; "anesthetic"). Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the second fluid source includes a needleless syringe for holding fluids. Moore teaches the second fluid source includes a needleless syringe (26) for holding fluids. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the

time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

11. In regards to claims 8 and 21, the Miller in view of Moore disclose the claimed invention, as set forth and cited above, and in addition Examiner notes that check valves inherently have a predetermined cracking pressure dictated by a change in pressure and Miller in view of Moore teaches the check valve within at least a portion of the biopsy device.

12. In regards to claims 10 and 23, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source. Moore teaches that it is desirable to keep the two fluid sources isolated and that fluid can not pass the check valves in a wrong direction (column 2, lines 15-18). Therefore, the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the

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art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

13. In regards to claims 27-30, Miller discloses the claimed invention, as set forth and cited above, except for expressly disclosing the body member comprising a housing comprising a unitary member. Moore teaches the body member comprising a housing comprising a unitary member (11) (as best seen in figure 1) (column 1 lines 63-69). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller and Moore. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller with the components as taught by Moore to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

14. Claims 11, 13, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller in view of Moore and further in view of Turturro et al. (US 6,331,165, hereinafter Turturro). Miller in view of Moore discloses the claimed invention, as set forth and cited above, except for expressly disclosing the first and second check valves including female luer fittings and the second fluid source includes a male luer fitting adapted to mate with the female luer fitting of the second check valve. Turturro teaches a biopsy system, comprising *inter alia*: luer fittings (column 18, lines 33-41) for the purpose of providing quick and easy connection and disconnection. Furthermore, the Examiner notes male and female luer fittings are well known in the art and routinely used. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Miller in view of Moore and Turturro. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Miller in view of Moore with the components as taught by Turturro to achieve the predictable results of providing a biopsy system with increased fluid management to simplify and save time in surgical procedures by providing additional and/or alternate fluid management configurations.

Response to Arguments

15. Applicant's arguments filed 02/16/2009 have been fully considered but they are not persuasive. Applicant argues the rejections of the claims under 35 U.S.C. 103(a) as being unpatentable under Miller in view of Moore.

16. In response to applicant's argument that Miller in view of Moore does not disclose the first check valve selectively opened when a vacuum is created in the fluid connector, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

17. In this case the biopsy system as disclosed, taught, and cited above by Miller in view of Moore and more particularly the check valve as taught by Miller is fully capable of "selectively opening when a vacuum is created in the fluid connector".

18. Moreover, the functional claim limitation Applicant appears to rely heavily upon for patentability comprising "wherein the first check valve is selectively opened when a vacuum is created in the fluid connector" does not structurally distinguish the claims from the applied prior art.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736